K001966

JUL 2 0 2000

510(k) Summary of Safety and Effectiveness

Prepared July 10, 2000

TRADE NAME	Rebar™ Micro Catheter (2.3F Rebar-18 micro catheters - 110, 130, 153 cm lengths)		
GENERIC NAME	Infusion Catheter	**CLASSIFICATION**	Class II (21 CFR 870.1210)
SUBMITTED BY	Micro Therapeutics, Inc. (MTI) 2 Goodyear Irvine, CA 92618	**CONTACT**	Maribelle Aguinaldo Regulatory Affairs (949) 837-3700
PREDICATE DEVICE	Micro Therapeutics, Inc. Rebar™ Micro Catheter, 510(k) K993672 (1.9F Rebar-14 and 2.9F Rebar-027 micro catheters: 110, 130, 153 cm lengths)		
DEVICE DESCRIPTION	The Rebar Micro Catheter is an endhole, single-lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter has a semi-rigid proximal shaft which transitions into the flexible distal shaft to facilitate the advancement of the catheter in the anatomy. Dual or single radiopaque markers at the distal end facilitate fluoroscopic visualizatoin. The outer surface of the catheter is coated to increase lubricity.		
INDICATIONS FOR USE	The Rebar Micro Catheter is indicated for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.		
SAFETY AND PERFORMANCE TESTS	Biocompatibility of the Rebar catheter has been verified in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices*. Test results confirmed biocompatibility of the Rebar catheter when tested as an external communicating, blood contact, short duration (<24 hrs.) device. Performance testing of the Rebar catheter was conducted in accordance with ISO 10555, *Sterile, single use intravascular catheters - Part 1*. Verification testing for changes implemented in the Rebar-18 catheters included dimensional inspection, hub integrity, flow rate measurements, burst strength, kink resistance, tensile strength, tip shape retention, and guidewire compatibility testing. These tests yielded acceptable results substantially equivalent to the predicate device.		
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The Rebar Micro Catheter is substantially equivalent to the predicate device in intended use and principles of operation.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2000

Ms. Maribelle Aguinaldo
Regulatory Affairs
Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K001966
Trade Name: Rebar™ Micro Catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: June 27, 2000
Received: June 28, 2000

Dear Ms. Aguinaldo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: _____

Device Name: Rebar™ Micro Catheter

Indications for Use: The Rebar Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)

(Division Sign-Off) K001966

Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____